REMARKS

Claims 89-102, 104-106, 108, 124, 125, 127-130, 132-135, 137-147, and 149-164. Claims 102, 144 and 156 stand withdrawn from consideration.

Claim Amendments

By this amendment, claims 89, 90, 93, 104, 105, 124, 127, 130, 135, 143, 146, 155 and 158 are amended. Claims 107, 121, 122, 123, 126, 131, 136 and 148 are cancelled. New claims 159-164 are added.

Objections to Claims

Claims 97, 100, 149, 150 and 158 stand objected to as depending from a rejected claim, but would be allowable if rewritten in independent form.

Also, claims 135-143 and 145 are indicated as being directed to allowable subject matter to the extent they are limited to the elected invention.

Interview with Examiner

Applicant thanks the Examiner for the courtesy extended toward his representative during the recent interview. During the interview, those distinctions that exist between the claimed invention and the cited prior art were discussed. No agreement was reached as to the withdrawal of the outstanding rejections. However, during the interview, the Examiner did indicate that the use of either copper gluconate or orotate would be allowable as a species of copper, while in his view, the salts for the remaining components would be limited to orotate salts.

Rejection under 35 USC 103(a)

Claims 89-96, 98, 99, 101, 103-108, 121-134, 146-148, 151-155 and 157 stand rejected under 35 USC 103(a) as being unpatentable over *Jackson* in view of *Riley et al*, *Wawretschek et al*, *Herschler '421*, *Herschler '039* and *Boumous et al.* This rejection is respectfully traversed to the extent deemed to apply to the claims as amended.

The claimed method is neither disclosed nor suggested by the cited prior art, as is apparent from the following discussion of the deficiencies of the prior art relied upon by the Examiner.

Jackson

Jackson discloses a dietary supplement for supplementing the micronutrient and phytochemical needs of women at various stages of their life cycle to prevent or reduce the risk of (not treat) a number of conditions, including some cancers. The supplement is a composition comprising copper, vitamin C and thirteen other components (including manganese, iron and zinc) in admixture with a biologically acceptable carrier (see column 2, line 34 to column 3, line 21).

The purpose of the compositions disclosed in *Jackson* is to supplement the specific micronutrient and phytochemical needs of a woman during each of her adult life stages, with the objective of generally promoting her well being, and thereby hopefully preventing or reducing various health risks to which she may, during this period, be exposed (see column 1, lines 4 to 9). One of the many health risks include "some cancers" (see column 1, lines 21 to 28). It is disclosed (see column 1, lines 26 to 28) that the incidence and risk of these conditions varies with each life stage and has been shown to be influenced by diet and dietary supplements.

There is, however, no suggestion in Jackson that the dietary supplements disclosed therein would be of any utility where ***treatment of cancer*** is concerned. As the skilled person would readily appreciate, while a dietary supplement may be of benefit in maintaining the general well being and health of an individual, and thus conversely have some utility in reducing the chances of that individual contracting cancer or some other form of disease or illness, this by no means raises any expectation that the supplement would be effective in treating cancer or other diseases once established.

Equally, the compositions disclosed in *Jackson* do not contain salicylic acid, or any alkali or alkaline earth metal salt thereof. Thus, there is no suggestion in *Jackson* that salicylic acid, or any alkali or alkaline earth metal salt thereof, would be useful even in reducing the risk of cancer being contracted, let alone that it would be of any use in *treating* cancer.

Riley

Riley discloses (see column 1, lines 20 to 26) a modular system of multivitamin and mineral supplementation to replace micronutrients lost as a result of lifestyle factors and inadequate diet thereby improving public health by insuring adequate intake of micronutrients needed for disease prevention. Modules 4, 5 and 6 of *Riley* contain aspirin, with Modules 5 and 6 further including copper, and vitamin C, together with 24 other components including manganese, iron and zinc (see Table II). It is furthermore stated (see column 6, line 62 to column 7, line 6) that the modular system can be used to reduce the risk of chronic diseases such as cancer (amongst others).

Again. however, and as with *Jackson*, there is in *Riley* no suggestion that the disclosed modular systems would be of any benefit in *treating* cancer.

Equally, whereas the claims of the present application require the use of salicylic acid or an alkali or alkaline earth metal salt thereof, Modules 4, 5 and 6 of *Riley* use aspirin, i.e. acetylsalicylic acid, which is not within the scope of the claims. Aspirin is used in *Riley* primarily for its anti-platelet aggregating capacity, so as to reduce the risk of coronary heart disease (see column 5, lines 9 to 13 and 31 to 39), although brief reference is made to it also being able *to reduce the risk of* certain cancers (column 16, lines 24 to 26). Moreover, as evidenced by the extracts from Martindale "The Complete Drug Reference", 32nd edition (1999) (of record), this anti-platelet aggregating capability only occurs with acetylated salicylates, i.e., it is present for aspirin but not for the claimed salicylic acid or salicylates.

While referring to aspirin *per se* in Table II, *Riley* does also state at certain other points that "aspirin or the like" may be used (see column 5, lines 9 to 14, column 16, lines 15 to 17, and column 21, lines 48 to 62). However, what is meant by this is further explained in column 21, lines 48 to 62. As explained in this passage, according to *Riley* either aspirin or a "bioequivalent thereof" should be used, or a compound used "which can be easily converted to aspirin". Amongst such compounds, salicylic acid and salicylates are listed, it being confirmed at lines 59 to 62 that the compound to be used should be "extracted, processed, tested, and utilised either as is (bioequivalent) or converted to acetylsalicylic acid (aspirin)".

As explained above, salicylic acid and alkali or alkaline earth metal salt thereof cannot, in the context of *Riley*, be considered bioequivalents of aspirin, it being common knowledge (see Martindale) that they lack the very anti-platelet aggregating capability for which aspirin is, in *Riley*, primarily used. Thus, there is in fact no suggestion in *Riley* to use salicylic acid, or any alkali or alkaline earth metal salt thereof, in the modular systems described therein, only that salicylic acid and salicylates may be a suitable source of acetylsalicylate (aspirin).

It follows, therefore, that, like *Jackson, Riley* also does not disclose the use of salicylic acid, or any alkali or alkaline earth metal salt thereof even in a composition for reducing the risk of cancer, let alone as part of a composition for treating cancer.

Wawretschek

Wawretschek discloses a means of reinforcing the pharmacological action of medicaments which exhibit an affinity for linking with blood proteins *in vivo* and *in vitro*. It is an object of the invention to find a means which is capable of providing a controlled increase of that portion of the drug to be used which is not bonded to the serum albumen (see column 1, lines 55-58) and that this is achieved by the use of orotic acid and/or a physiologically tolerable orotic acid salt.

In Example 5 of *Wawretschek* the analgesic efficacy of sodium salicylate is examined both alone and in a binary composition with choline orotate. There is no disclosure of the use of copper or vitamin C (or, for that matter, manganese, iron, sulphur or zinc). Moreover, there is no teaching whatsoever relating to the treatment neoplastic disease.

Herschler ('421)

Herschler '421 discloses (see column 1, lines 12 to 18) the use of methylsulphonylmethane ("MSM") to ameliorate the symptoms of stress (specifically gastrointestinal upset, inflammation of the mucous membranes and allergic reactions). In one example (Example VIII, column 12, lines 11 to 47), MSM is administered with and without ascorbic acid (Vitamin C) to treat mucous membrane inflammation at least partly associated with lung tumours. Treatment (both with and without Vitamin C) appears to have alleviated the patients' conditions, and caused significant regression of tumour mass.

Thus, *Herschler* teaches the use of compositions comprising MSM, optionally including Vitamin C, for the treatment of lung tumours and associated inflammation of the mucosa. However, there is no disclosure of the use of either copper or of salicylic acid, or an alkali or alkaline earth metal salt thereof, as part of a treatment for neoplastic disease.

Herschler ('039)

Herschler '039 discloses (see abstract) that MSM is an assimilable form of sulphur. It also discloses (see Example 36) that supplementation of diet with 2 wt % MSM can inhibit DMBA-induced mammary carcinoma in rats and (see Example 37) that supplementation of diet with 3 wt % MSM in water can protect against otherwise lethal spontaneous mouse lymphomas. As with *Herschler* '421, however, there is no disclosure of the use of either copper or of salicylic acid, or an alkali or alkaline earth metal salt thereof, as part of a *treatment for* neoplastic disease.

Bounous

Bounous discloses a formula diet comprising whey protein concentrate to enhance mammalian immune response. The formula diet consists of undenatured whey protein concentrate and a protein-free diet powder containing, among other components, "vitamins and minerals" (see column 6, lines 34 to 56). The "vitamins and minerals" include vitamin C and copper, together with 22 other components (including iron and zinc). It is disclosed (see column 24, lines 26 to 54) that the formula diet reduces the size of DMH-induced tumours in mice. However, according to this same passage (see in particular lines 39 to 41), this anti-cancer effect is indicated as being attributable purely to the whey protein. The vitamins and minerals appear to have only been added to meet the nutritional requirements of the mice (see column 6, lines 46 to 56) in the controlled conditions of the animal experiment being conducted.

There is no disclosure in *Bounous* that vitamin C or copper have any particular utility in treating cancer. Moreover, the compositions disclosed in *Bounous* do not contain salicylic acid, or an alkali or alkaline earth metal salt thereof, at all. Accordingly, there is no disclosure or suggestion in *Bounous* of using vitamin C and copper, in combination with salicylic acid, or an alkali or alkaline earth metal salt thereof, as a treatment for neoplastic disease.

Despite the above deficiencies of the teachings of the cited prior art, the Examiner continues to take the position that the claimed invention is an obvious variation of the cited prior art. Applicant traverses the position of the Examiner as recited as follows in the Office Action:

- At page 4 of the Office Action, first paragraph, the Examiner states in support of the rejection:

> *"The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the use of copper orotate, manganese orotate, iron orotate, sodium salicylate, a source of assimilable sulphur, proline and vitamin C.*

The difference between the prior art and the claimed invention is not merely a failure to "expressly" disclose the use of copper orotate, manganese orotate, sodium salicylate and vitamin C. The claims of the present application are directed to a method of treating neoplastic disease using a source of assimilable copper, a source of assimilable manganese, salicylate acid or an alkai or alkaline earth metal salt thereof, and vitamin C. By and large, the prior art cited by the Examiner does not relate to the treatment of a neoplastic disease at all. Therefore, taken as a whole, the difference between the prior art and the claimed invention is that the prior art discloses neither the claimed combination of components nor the claimed utility in treating cancer.

- At page 4 of the Office Action, first paragraph, the Examiner states in support of

the rejection:

> *"However, the prior art amply suggests the same as the prior art discloses dietary supplements which combine various nutrients, such as copper, manganese, vitamin C with salicylates for use in women and reducing the risk of cancer, the combination of sodium salicylate and salts of orotate to increase the efficacy of the sodium salicylate, the use of copper, manganese, iron and vitamin C for use in pregnant women and reducing the risk of cancer, MSM for treatment of cancer and proline which can be combined with other nutrients, such as copper, iron, zinc and vitamin C and is used to treat cancer."*

Applicant does not agree with the above analysis. That is, the prior art does not "amply suggest" the claimed invention. Jackson discloses dietary supplements, which do not include salicylate acid or a salt thereof, for solely for the purpose of promoting general well being and thereby hopefully reducing the risk of contracting numerous diseases. There is no suggestion that the compositions disclosed therein are of any utility in treating cancer.

Similarly, Riley discloses modular multi-vitamin and mineral supplementation, which modular system can include aspirin and bioequivalents thereof but not salicylic acid or the presently claimed saliclylates, with the objective of generally improving public health thereby reducing the risk of contracting chronic diseases. Again, there is no teaching that the modular system described is of any use in treating cancer. Wawretschek is concerned with the traditional analgesic efficacy of sodium salicylate and the improvement of this analgesic efficacy by combination with orotate salts. Again, there is no discussion of treating cancer. Hershler (both documents) teaches that the use of methylsulfonylmethane (MSM) has had some success in treating certain tumours, whether used with or without vitamin C. Bounous discloses that a whey protein formula diet, containing various vitamins and minerals added only to meet the nutritional requirements of mice, was effective in reducing the size of DMH-inducted tumours in mice.

Thus, to summarize, the combined teachings of the above cited prior art are limited to no more than: (1) that vitamin and mineral supplements can be used to improve general health (which may have an effect in reducing the risk of contracting diseases in general); (2) that aspirin (or similar acetylated salicylates), if added to vitamin supplements, may be beneficial in terms of general health and reducing the risk of contracting disease; (3) that sodium salicylate is a general analgesic whose analgesic effect can be improved by the addition of orotic acid or a tolerable orotate salt; (4) that MSM may have some efficacy in treating neoplastic disease; and (5) that a formula diet comprising whey protein may have some anti-neoplastic effect.

- At page 4 of the Office Action, first paragraph, the Examiner states in support of the rejection:

> *"As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art by providing the copper, iron, zinc and manganese as salts of orotate so as to increase the efficacy of the sodium salicylate and to combine copper, iron, zinc and manganese with sodium salicylate and vitamin C with the expectation that the composition would be suitable for use in pregnant women and for treatment of cancer, to further add proline with the expectation that the same would be suitable for treatment cancer and to add MSM as it is effective in treating cancer."*

As indicated above, there is no teaching in the prior art documents, whether read individually or in combination, that a composition comprising assimilable copper, assimilable manganese, salicylate acid or an alkai or alkaline earth metal salt thereof, and vitamin C would be effective in treating neoplastic disease. Consequently, it would not have been "well within" the ability of one of ordinary skill in the art, and one of ordinary skill would not have been "motivated to modify the prior art", to arrive at a method of treatment as currently claimed. As the majority of the cited prior art does not relate to treating neoplastic disease, it would not have been obvious to one of ordinary skill in the art to refer to such documents at all. The only

teaching relating to treating neoplastic disease is that compositions comprising MSM, and diets comprising whey protein, may have some benefit in treating neoplastic disease. There is nothing that suggests a composition as presently claimed would be effective.

- At the paragraph bridging pages 4 and 5 of the Office Action, the Examiner states in support of the rejection:

> *"In response to applicant's arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references. Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references."*

Applicant's arguments are not based on any of the above cited rationales. Rather, for reasons given above and in the applicant's previous response, applicant simply contends that the requirements for rejecting the application under 35 U.S.C. 103(a) have not been met – i.e., that the combined teachings of the references would not have suggested the claimed invention to one of ordinary skill in the art.

In order for a claimed invention to be considered obvious to one of ordinary skill in the art based on the combined teachings of several references, it must in the first instance have been obvious to one of ordinary skill in the art to combine those teachings. One of ordinary skill in the art to which the claimed subject matter pertains, namely, the treatment of neoplastic disease, would not have found it obvious to refer to documents concerned with overcoming difficulties in the fields of analgesia or general nutrition. Thus, one of ordinary skill in treating neoplastic disease would not have referred to Jackson, Riley, or Wawretschek at all. Moreover, even if for some unexplained reason the person of ordinary skill in this art were to have taken the non-obvious step of reading Jackson, Riely, Wawretschek, Hershler (both documents) and Bounous

in combination, the totality of such teachings merely indicates that MSM compositions and whey protein diets may have some benefit in treating neoplastic disease. It would therefore have not been obvious to one of ordinary skill in the art to attempt using, as a treatment for neoplastic disease, a composition comprising a combination of: assimilable copper; assimilable manganese; salicylic acid or an alkai or alkaline earth metal salt thereof; and vitamin C, because the combined teachings of the cited references would not have suggested that such a composition would have had any efficacy in treating neoplastic disease in a patient already suffering from such a disease.

- At page 5 of the Office Action, second paragraph, the Examiner states in support of the rejection:

> *"The Applicant argues that Wawretschek is not concerned with treatment of cancer, and, thus is irrelevant. The Applicant provides no evidence that increasing the analgesic effect of a compound is irrelevant in the treatment of cancer."*

The question to be addressed is whether or not it would have been *obvious* to one skilled in the art *from Wawretschek* that increasing the analgesic effect of the salicylic acid would have resulted in a composition beneficial in treating cancer. Absent any teaching in Wawretschek regarding the treatment of cancer, it cannot have been obvious to one of ordinary skill in the art that the disclosed effects in terms of analgesia would have translated in any way to efficacy in treating neoplasic disease.

Even if the compositions disclosed in Wawretschek are effective in treating cancer (and the reference does not state one way or the other), this is immaterial in view of the fact that Wawretschek does not *disclose* that they are effective in treating cancer and it would therefore

not have been obvious that they were effective in treating cancer. The fact that a compound, disclosed in a prior art document as having one effect, might possibly have a hidden further therapeutic effect, cannot render this hidden further therapeutic effect obvious – otherwise it would never be possible to obtain a patent for a newly discovered therapeutic use of a compound having an existing therapeutic use.

- At page 5 of the Office Action, second paragraph, the Examiner states in support of the rejection:

> *"Similarly, with respect to Jackson and Riley, the Applicant provides not evidence that providing multivitamins and nutrients would not provide a nutritional benefit to cancer patients. The claims are directed to treating a neoplastic disease, however, the claims do not exclude treatment in terms of providing nutritional benefit to the cancer patient."*

Again, the issue to be addressed is whether the teachings of Jackson and Riley would have made it obvious to one of ordinary skill in the art that a composition as presently claimed would be effective in treating cancer, not whether the prior art multivitamin and nutrient compositions do, or do not, provide any undisclosed efficacy in treating cancer in a patient.

Treating a neoplastic disease self evidentially involves retarding, halting and/or reversing tumour growth and/or progression, for example, halting/retarding a solid tumour growth as demonstrated in Examples 11, 12 and 13 of the present application, and/or achieving partial/complete remission in patients suffering from benign or malignant tumours as demonstrated in Examples 14 to 18 of the present application. Given the increasing prevalence of cancer, the fatal character of most tumours if left untreated, and the significant increase in patient life expectancy in the event of successful treatment, the importance of finding effective new treatments for neoplastic disease cannot be understated.

Conversely, the compositions described in Jackson and Riley are disclosed as multivitamin and mineral supplements. They are administered for solely nutritional purposes (i.e. to ensure vitamin and mineral intake is in accordance with recommended daily levels), so as to improve the user's general health and, indirectly, therefore reduce the risk of contracting diseases. This purpose in no way equates to the purpose of retarding, halting, or reversing tumour growth in a patient who is already suffering from neoplastic disease. Indeed, it is not plausible to suggest that a doctor or patient, on finding that the patient is suffering from a tumour (and may as a result have only a limited life expectancy), would consider administering/using a multivitamin supplement designed only to be used to ensure daily intake is at generally recommended levels, instead of a demonstrated treatment for neoplastic disease.

The claims of the patent are directed to a method of treating neoplastic disease in a patient. In order for a method to fall within the scope of the claims of the present application, a composition must be administered to a patient suffering from neoplastic disease in order to treat said disease – i.e., it must be administered *with this purpose in mind.* Administration of the composition for a different purpose does not fall within the scope of the claim, even if a neoplastic disease is thereby inadvertently, and perhaps unknowingly, treated. If this were not the case, it would in many cases not be possible to obtain a patent for a new and inventive therapeutic use of a compound having an existing therapeutic use, as the prior administration of the compound for its previous use may have resulted in the new therapeutic effect having unknowingly taken place (for example in patients who were unaware that they were suffering from the disease to which the new therapeutic use is directed, or were suffering from said disease but were also taking a different medicament for that disease).

Thus, the multivitamin and mineral supplements disclosed in Jackson and Riley do not render obvious the presently claimed methods of treating neoplastic disease in a patient using the claimed active ingredients.

- At page 5 of the Office Action, second paragraph, the Examiner states in support of the rejection:

> *"It cannot be concluded from the working example that each of the components contributed to the observed effect. In fact, it is equally possible that one or more of the components provide no benefit other than a nutritional benefit."*

The data provided in the present application (cf Examples 11 to 18) clearly demonstrates that a composition consisting of active ingredients (a) to (d) as claimed in Claim 89 as amended (i.e. an assimilable source of copper, salicylic acid or an alkali or alkaline earth metal salt thereof, vitamin C, and an assimilable source of manganese) had a striking effect in treating cancer.

In contrast, none of the cited prior art indicates that any of these components, whether administered alone or in any combination of said components, is effective in treating neoplastic disease. Certainly, the applicant is not aware of any prior art that indicated that any of the components, taken on their own, provided the striking anti-neoplastic effects now demonstrated in the present application and attached documents when using the claimed combination of these components.

It is submitted that this contrast, between the results achieved using the claimed combination of components and the previously known effects of said components individually, does indicate that *prima facie* the claimed components are having a synergistic effect and that all contribute to the treatment of the neoplastic disease.

It is accepted, of course, that one or other components may be making a greater or lesser contribution and may be of more or less importance. However, it is not seen that this is of any relevance to the issue of obviousness (or, indeed, enablement). The applicant has convincingly demonstrated that the claimed compositions (comprising components (a) to (d)) are effective in treating neoplastic disease. Conversely, the cited prior art does not indicate that any of the components would be effective in treating such diseases. The use of the claimed combination in the claimed methods of treatment is therefore non-obvious.

- At page 5 of the Office Action, second paragraph, the Examiner states in support of the rejection:

> *"Also, the working example does not support the entire scope of the claims as the working example treated a specific tumour with a combination of the specified components in the specified amounts."*

In each of the examples in the present application, a composition is administered consisting of: (a) an assimilable source of copper; (b) salicylic acid or an alkali or alkaline earth metal salt thereof; (c) vitamin C; and (d) an assimilable source of manganese. This corresponds to the requirements of the claims as amended.

The examples of the present application demonstrate successful treatment of not just one specific tumour, but of a diverse variety of different tumours, i.e. thymoma tumour (Examples 11 and 13), mammary carcinoma (Example 12), spindle cell tumour (Example 14), infiltrating malignant neoplasm of the urethra (Example 15), nasal tumour (Example 16), carcinoma of the peritoneum (Example 17), and T-cell lymphoma (Example 18). Thus, the examples do demonstrate the broad applicability claimed for the compositions.

Equally, the examples demonstrate successful treatment using more than one salt form of the claimed active ingredients. Specifically, whereas copper orotate is used in most of the

examples, copper gluconate is used in Example 13 and is shown to be effective. Equally, whereas manganese orotate is used in the examples of the application, manganese gluconate is the salt form used in the clinical trials described in the attached documents. Thus, the applicant has provided proof of principle that different salt forms of, for example, copper and manganese can be used, it being the presence of the active ingredients as claimed which is critical, not the specific assimilable form used. A wide variety of different forms of assimilable metal are conventionally used in the Pharmaceutical art, as for example are listed on page 2 of the application, lines 12 to 28. Further commonly used salt forms can easily be ascertained (see, for example, the entries for Copper and Manganese in the 1999 edition of Martindale, copy submitted herewith. It would be a matter of mere routine for one skilled in the art to prepare different salt or other assimilable forms of the active ingredients, and test these forms in order to select the forms most suitable for his or her purpose (based, for example, on the species of the patient and/or the excipients in the formulation be used).

Likewise, the examples use a variety of different weights of the various active ingredients, and it would again be a matter of mere routine for one skilled in the art, based on the teaching of the present application clearly demonstrating the efficacy of the claimed combination of actives in treating a variety of cancers in a variety of patients, to select appropriate amounts of each active based on the patient's requirements (for example, based on the species of the patient, age, body mass, etc.).

It is therefore respectfully submitted that the scope of the claims as amended is fully supported by the disclosure of application. It would be unduly restrictive to require the applicant to limit its claims to specific cancers, assimilable forms of active, or amounts of active agent. The applicant has demonstrated the broad applicability of its inventive concept of using a

combination of an assimilable source of copper, salicylic acid or an alkali or alkaline earth metal salt thereof, vitamin C, and an assimilable source of manganese, in treating neoplastic disease, and third parties should not be afforded the opportunity of making unfair use of the invention, by relying on the teaching of the application and merely making such routine and commonplace alterations as, for example, substituting a different commonly used salt form for one of the salt forms expressly disclosed in the exemplified embodiments.

The Examiner states that the test for obviousness is not that the claimed invention must be expressly suggested in any one or all of the cited prior art, but rather what the combined teachings of the prior would have suggested to those of ordinary skill in the art. Even using this test, applicant maintains that a method of treating neoplastic disease, as presently claimed, is not taught by the combined teachings of the prior art.

In order to assess what is obvious from the combined teachings of the prior art, one must first consider whether the combination of documents necessary to arrive at the claimed subject matter is, in fact, an obvious one to make. To put it another way, one cannot assert obviousness based on or combining (based on hindsight knowledge of the claimed invention) selected teachings from various prior art documents if, based on the common knowledge the person skilled in the art, it would not have been obvious to combine the various documents in the first place.

In this regard, the presently claimed invention is, as noted above, a method of treating neoplastic disease, successful treatment having been demonstrated in Examples 11 to 18 of the present application. Thus, the initial question to be asked is whether the skilled person, if seeking to develop ***a novel treatment for neoplastic disease***, would have referred to certain of the cited prior art at all.

As noted in the analysis presented above, *Wawretschek* is not concerned with the treatment of cancer at all. Thus, the compositions taught in this document must be considered irrelevant for the purposes of the present invention, since it cannot plausibly be suggested that it would have been obvious to one of ordinary skill in the art to start considering documents relating to, for example, analgesia, when seeking new treatments for cancer.

Similarly, neither *Jackson* nor *Riley* relate to *treatment* for cancer. Instead, these documents are concerned with multivitamin and nutrient compositions intended to improve general health and so reduce the *risk of* contracting diseases (such as cancer).

Again, it is respectfully submitted that it would not have been obvious to the skilled person to refer to documents dealing with general nutrition and health, when attempting to devise new treatments for neoplastic disease. Utility in preventing cancer from appearing, by way of improving general health and diet, does not equate to an obvious utility in treating cancer. By way of a simple example, it is well known that dietary fibre is recommended as a means of reducing the risk of contracting bowel cancer, but equally obviously the usual treatments for bowel cancer are radio-chemotherapy and/or surgery, not eating more fibre.

Thus, again, the skilled person would not have found it obvious to refer to either of these documents. Moreover, even had the skilled person referred to *Jackson* or *Riley*, he would not have considered either document to suggest any methods of treating cancer, since neither document asserts that the compositions disclosed therein have any use in treating cancer or provides any data (clinical, animal, or even *in vitro*) to suggest the same.

Herschler and *Bounous* do disclose compositions having apparent utility in treating at least some forms of cancer. However, these documents teach that, respectively, MSM (either with or without Vitamin C) has utility in reducing tumour mass, and whey protein (with vitamin

supplements to support the general health of the mice in the study) has utility in reducing tumours. Thus, even if the skilled person were to have read these documents in combination, the combination would have fallen far short of teaching that copper, salicylic acid or an alkali or alkaline earth metal salt thereof, vitamin C, and a source of manganese, should be combined and used as a treatment for neoplastic disease.

Finally, it should be noted that, even if the skilled person were to have taken the step of reading *Jackson* and *Riley* in combination with *Herschler* and *Bounous*, and taken the step of attempting to use some combination of the various components of these compositions as a treatment for neoplastic disease (despite the fact that neither *Jackson* or *Riley* give any indication that the compositions in these documents are effective in treating cancer), he still would not have arrived at the claimed subject matter, since none of these documents teach the use of *salicylic acid or an alkali or alkaline earth metal salt thereof* (the definition, in *Riley*, of bioequivalents of aspirin not encompassing these compounds, for the reasons given above). The only document to disclose the use of salicylic acid or an alkali or alkaline earth metal salt thereof is *Wawretschek*, in which sodium salicylate is used for its conventional purpose as an analgesic, there being therefore no reason from this document (or any of the others cited) to use sodium salicylate as part of a treatment for cancer.

It is therefore respectfully concluded that, contrary to the assertion of the Examiner in the Action, there would in fact have been no motivation for one of ordinary skill in the art to use copper, salicylic acid, vitamin C, and a source of manganese, to treat neoplastic disease, as required by the claims of the present application as amended, and such a method would not have been obvious one of ordinary skill in the art.

The rejection under 35 USC 103(a) is this without basis and should be withdrawn.

The application is now in condition for allowance. Allowance of claims directed to the generic invention is believed proper.

Payment in the amount of $225 is submitted herewith as payment for the requested two month extension of time.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By _____

James W. Hellwege, #28,808
P.O. Box 747
Falls Church, VA 22040-0747
(703) 205-8000

JWH/ej
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